

GP 1632  
PATENTS

CERTIFICATE OF MAILING

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Alicia J. Hager, Reg. No. P-44,180

Date

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re Application of

MAR 1 1999

Ivarie et al.

MAIL ROOM SPECIAL  
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Serial No: 09/173,864

: Group Art Unit: 1632

Filed: October 16, 1998

: Examiner: Not assigned

For: NOVEL VECTORS IN AVIAN TRANSGENESIS

Assistant Commissioner for Patents  
Washington, DC 20231

Sir:

TRANSMITTAL LETTER FOR INFORMATION DISCLOSURE STATEMENT

Transmitted herewith for filing in the above-entitled patent application is an Information Disclosure Statement, in compliance with 37 CFR 1.97, with referenced documents 1 through 66. Also included is a return postcard.

- [X] The Information Disclosure Statement is being submitted: (a) within three months of the filing date, or (b) before the mailing date of the first Office action on the merits. **Therefore, no fee is due under 37 CFR 1.97(b).**
- [ ] The Information Disclosure Statement is submitted more than three months after the filing date and after the mailing date of the first Office action on the merits, but, before a final action under § 1.113 or a notice of allowance under § 1.311. Applicant(s)' attorney hereby certifies under 37 CFR 1.97(e)(1) that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office on a counterpart foreign application not more than three months prior to the filing of the Statement. **Therefore, no fee is due under 37 CFR 1.97(c).**
- [ ] The Information Disclosure Statement is submitted more than three months after the filing date and after the mailing date of the first Office action on the merits, but, before a final action under § 1.113 or a notice of allowance under § 1.311. Applicant(s)' attorney hereby certifies under 37 CFR 1.97(e)(2) that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a foreign counterpart application, or, to the undersigned Attorney's knowledge after making reasonable inquiry, was known to any person designated in

§1.56(c) more than three months prior to the filing of the Statement. **Therefore, no fee is due under 37 CFR 1.97(c).**

**Deposit Account Authorization**

- ☐ The Information Disclosure Statement is submitted more than three months after the filing date and after the mailing date of the first Office action on the merits, but, before a final action under § 1.113 or a notice of allowance under § 1.311, without certification under 37 CFR 1.97(e). Therefore, *only if this entry is checked in the left margin*, the **\$240.00** fee set forth in §1.17(p) is authorized below.
- ☐ The Information Disclosure Statement is submitted after the mailing date of a final action under § 1.113 or a notice of allowance under § 1.311, but before payment of the issue fee.
- ☐ Applicant(s)' attorney hereby certifies under 37 CFR 1.97(e)(1) that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office on a counterpart foreign application not more than three months prior to the filing of the Statement.
- ☐ Applicant(s)' attorney hereby certifies under 37 CFR 1.97(e)(2) that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a foreign counterpart application, or, to the undersigned Attorney's knowledge after making reasonable inquiry, was known to any person designated in §1.56(c) more than three months prior to the filing of the Statement.

Applicant(s) hereby petition requesting consideration of the Information Disclosure Statement. Therefore, *only if this entry is checked in the left margin*, the **\$240.00** petition fee set forth in § 1.17(i)(1) is authorized below.

- ☐ Please charge \$\_\_\_\_\_ to Deposit Account No. \_\_\_\_\_.
- ☒ The Commissioner is hereby authorized to charge any additional fees or credit any overpayment to Deposit Account No. 08-1641. This is not, however, an authorization to pay the issue fee. A duplicate of this document is enclosed.

Respectfully submitted,



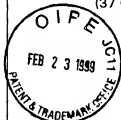
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# INFORMATION DISCLOSURE STATEMENT

(37 C.F.R. 1.56, 1.97, and 1.98)



SHEET 1 OF 5

ATTORNEY DOCKET

APPLICATION NO.

24011-0002

09/173,864

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## U.S. PATENT DOCUMENTS

† EX'R INITIAL	REF. #	PATENT NUMBER	DATE (MO/YR)	NAME	U.S. CLASS/ SUBCLASS	FILING DATE (if appropriate)
SK	1	4,959,317	09/90	Sauer	435/172.3	
SK	2	4,997,763	03/91	Hughes et al.	435/172.3	
SK	3	5,162,215	11/92	Bosselman et al.	435/172.3	
SK	4	5,304,489	04/94	Rosen	435/320.1	
SK	5	5,378,618	01/95	Sternberg et al.	435/172.3	
SK	6	5,464,764	11/95	Capecchi et al.	435/172.3	
SK	7	5,487,992	01/96	Capecchi et al.	435/172.3	
SK	8	5,677,177	10/97	Wahl et al.	435/325	
SK	9	5,741,957	04/98	Deboer et al.	800/2	

## FOREIGN PATENT DOCUMENTS

† EX'R INITIAL	REF. #	PATENT NUMBER	DATE (MO/YR)	COUNTRY	TRANSLATION (YES/NO)
SK	10	WO 90/11355	10/90	PCT	NO
SK	11	0 424 027 A1	04/91	EPO	NO
SK	12	0 424 044 A1	04/91	EPO	NO
SK	13	WO 94/20608	09/94	EPO	NO
SK	14	WO 97/47739	12/97	PCT	NO
SK	15	WO 98/01027	01/98	PCT	NO

## OTHER DOCUMENTS

† EX'R INITIAL	REF. #	CITATION (Author, Article Title, Journal/Book Title, Date, Pertinent Pages, etc.)
SK	16	Allioli et al., "Use of retroviral vectors to introduce and express the $\beta$ -galactosidase marker gene in cultured chicken primordial germ cells," <i>Developmental Biology</i> , 165:30-37 (1994).
SK	17	Archer et al., "Human growth hormone (hGH) secretion in milk of goats after direct transfer of the hGH gene into the mammary gland by using replication-defective retrovirus vectors," <i>Proc. Natl. Acad. Sci. USA</i> , 91:6840-6844 (1994).

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# INFORMATION DISCLOSURE STATEMENT

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## OTHER DOCUMENTS

† EX'R INITIAL	REF. #	CITATION (Author, Article Title, Journal/Book Title, Date, Pertinent Pages, etc.)
Sh	18	Bayley et al., "Exchange of gene activity in transgenic plants catalyzed by the Cre-lox site-specific recombination system," <i>Plant Molecular Biology</i> , 18:353-361 (1992).
Sh	19	Beato, M., "Gene regulation by steroid hormones," <i>Cell</i> , 56:335-344 (1989).
Sh	20	Bonifer et al., "Tissue specific and position independent expression of the complete gene domain for chicken lysozyme in transgenic mice," <i>The EMBO Journal</i> , 9:2843-2848 (1990).
Sh	21	Bosselman et al., "Germline transmission of exogenous genes in the chicken," <i>Science</i> , 243:533-535 (1989).
Sh	22	Brazolot et al., "Efficient transfection of chicken cells by lipofection, and introduction of transfected blastodermal cells into the embryo," <i>Molecular Reproduction and Development</i> , 30:304-312 (1991).
Sh	23	Briskin et al., "Heritable retroviral transgenes are highly expressed in chickens," <i>Proc. Natl. Acad. Sci. USA</i> , 88:1736-1740 (1991).
Sh	24	Brown et al., "Conformational alterations in the proximal portion of the yeast invertase signal peptide do not block secretion," <i>Mol. Gen. Genet.</i> , 197:351-357 (1984).
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Sh	26	Chung et al., "A 5' element of the chicken $\beta$ -globin domain serves as an insulator in human erythroid cells and protects against position effect in drosophila," <i>Cell</i> , 74:505-514 (1993).
Sh	27	Cosset et al., "Improvement of avian leukosis virus (ALV)-based retrovirus vectors by using different cis-acting sequences from ALVs," <i>Journal of Virology</i> , 65:3388-3394 (1991).
Sh	28	Cosset et al., "Use of helper cells with two host ranges to generate high-titer retroviral vectors," <i>Virology</i> , 193:385-395 (1993).
Sh	29	Dean et al., "Regulation of th chicken ovalbumin gene by estrogen and corticosterone requires a novel DNA element that binds a labile protein, chirp-1," <i>Molecular and Cellular Biology</i> , 16:2015-2024 (1996).
Sh	30	Dierich et al., "Cell-specificity of the chicken ovalbumin and conalbumin promoters," <i>The EMBO Journal</i> , 6:2305-2312 (1987).

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## OTHER DOCUMENTS

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SL	31	Dugaiczek et al., "The ovalbumin gene: cloning and molecular organization of the entire natural gene," <i>Proc. Natl. Acad. Sci. USA</i> , 76:2253-2257 (1979).
SL	32	Etches et al., "Contributions to somatic and germline lineages of chicken blastodermal cells maintained in culture," <i>Molecular Reproduction and Development</i> , 45:291-298 (1996).
SL	33	Fisher et al., "Expression of exogenous protein and analysis of morphogenesis in the developing chicken heart using an adenoviral vector," <i>Cardiovascular Research</i> , 31:E86-E95 (1996).
SL	34	Gannon et al., "Organisation and sequences at the 5' end of a cloned complete ovalbumin gene," <i>Nature</i> , 278:428-434 (1979).
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SL	39	Kaye et al., "A close association between sites of Dnase I hypersensitivity and sites of enhanced cleavage by micrococcal nuclease in the 5'-flanking region of the actively transcribed ovalbumin gene," <i>The EMBO Journal</i> , 3:1137-1144 (1984).
SL	40	Lai et al., "The ovalbumin gene: structural sequences in native chicken DNA are not contiguous," <i>Proc. Natl. Acad. Sci. USA</i> , 75:2205-2209 (1978).
SL	44	Lin et al., "Integration and germ-line transmission of a pseudotyped retroviral vector in zebrafish," <i>Science</i> , 265:666-669 (1994).
SL	42	Lobe et al., "Conditional genome alteration in mice," <i>BioEssays</i> , 20:200-208 (1998).
SL	43	Logie et al., "Ligand-regulated site-specific recombination," <i>Proc. Natl. Acad. Sci. USA</i> , 92:5940-5944 (1995).
SL	44	Lou et al., "Adenovirus-mediated gene transfer into tendon and tendon sheath," <i>Journal of Orthopaedic Research</i> , 14:513-517 (1996).

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# INFORMATION DISCLOSURE STATEMENT

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## OTHER DOCUMENTS

† EX'R INITIAL	* REF. #	CITATION (Author, Article Title, Journal/Book Title, Date, Pertinent Pages, etc.)
SL	45	Love et al., "Transgenic birds by DNA microinjection," <i>Bio/Technology</i> , 12:60-63 (1994).
SL	46	Moore et al., "The development of $\beta$ -lactamase as a highly versatile genetic reporter for eukaryotic cells," <i>Analytical Biochemistry</i> , 247:203-209 (1997).
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SL	48	Nordstrom et al., "A complex array of double-stranded and single-stranded DNA-binding proteins mediates induction of the ovalbumin gene by steroid hormones," <i>The Journal of Biological Chemistry</i> , 268:13193-13202 (1993).
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SL	50	Odell et al., "Seed-specific gene activation mediated by the <i>cre/lox</i> site-specific recombination system," <i>Plant Physiol.</i> , 106:447-458 (1994).
SL	51	Otten et al., "The MMTV LTR promoter is induced by progesterone and dihydrotestosterone but not by estrogen," <i>Molecular Endocrinology</i> , 2:143-147 (1988).
SL	52	Palmiter, R.D., "Quantitation of parameters that determine the rate of ovalbumin synthesis," <i>Cell</i> , 4:189-197 (1975).
SL	53	Palmiter, R.D., "Rate of ovalbumin messenger ribonucleic acid synthesis in the oviduct of estrogen-primed chicks," <i>The Journal of Biological Chemistry</i> , 248:8260-8270 (1973).
SL	54	Park et al., "Modulation of transcriptional activity of the chicken ovalbumin gene promoter in primary cultures of chicken oviduct cells: effects of putative regulatory elements in the 5'-flanking region," <i>Biochemistry and Molecular Biology International</i> , 36:811-816 (1995).
SL	55	Roop et al., "Definition of the 5' and 3' ends of transcripts of the ovalbumin gene," 19:63-68 (1980).
SL	56	Royal et al., "The ovalbumin gene region: common features in the organisation of three genes expressed in chicken oviduct under hormonal control," <i>Nature</i> , 279:324-331 (1997).
SL	57	Rucker et al., "Cre-mediated recombination at the murine whey acidic protein (mWAP) locus," <i>Molecular Reproduction and Development</i> , 48:324-331 (1997).

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1 EX'R INITIAL	REF. #	CITATION (Author, Article Title, Journal/Book Title, Date, Pertinent Pages, etc.)
SL	58	Sanders et al., "Positive and negative regulatory elements control the steroid-responsive ovalbumin promoter," <i>Biochemistry</i> , 27:6550-6557 (1988).
SL	59	Sauer, B., "Manipulation of transgenes by site-specific recombination: use of cre recombinase," <i>Methods in Enzymology</i> , 225:890-900 (1993).
SL	60	Schweers et al., "A protein with a binding specificity similar to NF- $\kappa$ B binds to a steroid-dependent regulatory element in the ovalbumin gene," <i>The Journal of Biological Chemistry</i> , 266:10490-10497 (1991).
SL	61	Thoraval et al., "Germline transmission of exogenous genes in chickens using helper-free ecotropic avian leukosis virus-based vectors," <i>Transgenic Research</i> , 4:369-376 (1995).
SL	62	Uyeda et al., "Cloning and sequencing of hen magnum cDNAs encoding vitelline membrane outer layer protein I (VMO-I)," <i>Gene</i> , 144:311-312 (1994).
SL	63	Vick et al., "Transgenic birds from transformed primordial germ cells," <i>Proc. R. Soc. Lond. B</i> , 179-183 (1993).
SL	64	Yee et al., "Generation of high-titer pseudotyped retroviral vectors with very broad host range," <i>Methods in Cell Biology</i> , 43:99-112 (1994).
SL	65	Zhang et al., "Inducible site-directed recombination in mouse embryonic stem cells," <i>Nucleic Acids Research</i> , 24:543-548 (1996).
SL	66	Zolotukhin et al., "A "humanized" green fluorescent protein cDNA adapted for high-level expression in mammalian cells," <i>Journal of Virology</i> , 70:4646-4654 (1996).

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